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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,216	06/24/2004	Yuichi Hikichi	61534 (46342)	3278

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EXAMINER	
MEAH, MOHAMMAD Y	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,216	HIKICHI ET AL.	
	Examiner	Art Unit	
	Mohammad Meah	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *1-11,13-18 and 20-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12, 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 04/22/05. & 06/24/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant, on date 10/12/2005 elected Group V (claims 12 and 19) for examination.

Election/Restriction

The applicant, on date 10/12/2005 elected without traverse Group V (claims12 and 19), drawn to methods of screening preventive/therapeutic agent for cancer or an apoptosis inducer using protein having the same or substantially the same sequence as that shown in SEQ ID NO: 1 for examination. Therefore groups I-IV and VI-X (claims 1-11, 13-18 and 20-22) of election/restriction-office action of date 09/14/2005 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected invention.

Priority

Acknowledgement is made of applicant's PCT priority date based on application filing date of 12/27/2002 in Japan # PCT/JP02/13640.

Claim Rejections

35 U.S.C 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete. The claims recite methods of using a protein to screen for cancer preventive/therapeutic agents or apoptosis inducers but do not define **how** the protein is used. What action comprise the claimed methods.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 19 are rejected under U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor at the time the application was filed, had possession of the claimed invention. These claims are directed to methods of identifying preventive/therapeutic agents for cancer or apoptosis inducer using a genus of protein that are substantially the same amino acid sequence (i.e.,50% to 95% identity to as defined on page 6 of the specification) to SEQ ID NO: 2 or fragments thereof.

The specification does not contain any disclosure of the methods of identifying preventive/therapeutic agents for cancer or apoptosis inducer using all functionally different proteins that are substantially the same amino acid sequence (50% to 95% identity to) to SEQ ID NO: 2 or fragments thereof. The genus of proteins that comprise these above amino acid sequences is a large variable genus with the potentiality involving many different proteins. Therefore, many functionally unrelated proteins are used within the scope of the methods claimed, including partial amino acid sequences. The specification discloses use of only a single species of the claimed genus, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 12 and 19 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying inhibiting agents for histone methyl transferase of SEQ ID NO: 1 and then identifying the agents to use as a therapeutic agent for a specific cancer not reasonably provide enablement for methods of identification of inhibiting agents for any protein that is substantially the same amino acid sequence (50% to 95% identity to) to SEQ ID NO: 1 or fragments thereof and then identifying the agents to use as preventive/ therapeutic agent for any cancer.

Claims 19 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying inhibiting agents for histone methyl transferase of SEQ ID NO: 1 and then identifying the agents to use as a specific cell-type apoptosis inducer not reasonably provide enablement for methods of identification of inhibiting agents for any protein that is substantially the same as (50% to 95% identity to) SEQ ID NO: 1 or fragments thereof and then identifying the agents to use as any cell-type apoptosis inducer.

Claims 12 and 19 are so broad as to encompass methods of for identifying inhibiting agents for proteins that are substantially the same amino acid sequence (50% to 95% identity to) to SEQ ID NO: 1 or fragments thereof and then identifying the agents to use as preventive/ therapeutic agent for any cancer or apoptiosis inducer. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of protein broadly used by the methods of the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only one histone methyl transferase

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass methods of using any protein having 50% identity to SEQ ID NO: 1 or any fragment thereof because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting histone methyl transferase activity; (B) the general tolerance of histone methyl transferase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any histone methyl transferase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including use of any protein with an enormous number of amino acid modifications of the histone methyl transferase of SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of

enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of histone methyl transferase for using the claimed methods having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

CLAIM Rejection - 35 U.S.C 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Jenuwein et al. (US PAT 6689583). Jenuwein et al. teaches methods of screening modulators of Human SUV3 protein (chromatin- regulatory protein) of SEQ ID NO: 4 which has 100% sequence identity with the SEQ ID NO: 1 of the present application and suggested their use as therapeutic agents for cancer and apoptosis inducer.

Claims 12 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Jenuwein et al. (US PAT 6555329 B2). Jenuwein et al. teaches methods of screening modulators of histone methyl transferase and suggested them as therapeutic agent for cancer and apoptosis inducer. Since claims 12 and 19 involve methods comprising using a partial peptide of SEQ ID NO: 1 or a protein substantially the same as (i.e. at least 50% identical to SEQ ID NO: 1), Jenuwein's methods of screening modulators of

histone methyl transferases of SEQ ID NO: 7 (has 56.1% sequence identity with SEQ ID NO: 1 of the present application) of claim 6, page 54, column 2) anticipates claims 12 and 19.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mohammad Younus Meah, PhD

Examiner, Art Unit 1652

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